Department of State Health Services Council Agenda Memo for State Health Services Council August 28-29, 2013

Agenda Item Title: Amendments to rules concerning the control of communicable diseases
Agenda Number: 4.a
Recommended Council Action: For Discussion Only
X For Discussion and Action by the Council

Background:

The Infectious Disease Prevention Section, Infectious Disease Control Unit Branch, located in the Disease Control and Prevention Services Division, provides services to prevent, control, and reduce infectious disease.

Such services include:

- investigating clusters of foodborne illnesses to identify contaminated food sources and remove them from circulation;
- recommending control measures (e.g. staying home from school, disinfection) to stop the spread of communicable diseases; and
- arranging diagnostic testing of persons with suspected communicable diseases.

Funding to the Infectious Disease Control Unit is provided through the Centers for Disease Control and Prevention (CDC) federal funds and through state general revenue funds.

Summary:

The purpose of the amendments is to update and clarify the rules concerning the control of communicable diseases. The amendments adjust the list of reportable diseases to include diseases and conditions of concern to public health.

The amendments add newly emerging infectious conditions that have received international attention. Texas is complying with guidance from the CDC regarding surveillance for these conditions. The amendments add two conditions to the notifiable conditions list that are infectious diseases which have recently emerged as significant concerns in the U.S. populations.

The rule changes:

- add the reporting of novel corona virus and carbapenem resistant *Enterobacteriacea* (CRE) as notifiable conditions;
- clarify language related to meningococcal meningitis;
- update exclusion criteria for school children with infectious diseases; and
- update definitions and agency references.

The rules will impact the people of Texas whose risk of illness is decreased by early detection, control, or prevention of infectious diseases in the community.

Key Health Measures:

The proposed amendments update and clarify rule language and add the new conditions as outcome measures. DSHS staff monitor more than 70 conditions known as "notifiable conditions." Health care providers, including physicians, infection preventionists, laboratorians, and school nurses, notify DSHS when these conditions are observed. DSHS staff then coordinate indicated interventions with providers and local health departments to minimize risk factors for the affected population. Adding these two new conditions will allow staff to monitor population rates and trends for these conditions in Texas. Because these are newly emergent infectious diseases, staff anticipate that the number of reported events will be small for both conditions and thorough rapid surveillance will enable public health to control or prevent transmission by implementing interventions quickly.

Summary of Input from Stakeholder Groups:

The Infectious Disease Control Unit solicited preliminary verbal feedback from stakeholders. Stakeholders included hospital infection preventionists, local and regional health departments, the Texas Medical Association, Texas Association of Local Health Organizations, Texas Hospital Association, DSHS Laboratory Services Section, DSHS TB/HIV/STD/Viral Hepatitis Unit, and DSHS Zoonosis Branch.

Stakeholder feedback focused on the change in school administration of a condition and readmission criteria for a child suspected of having meningitis, bacterial. This change was to make it consistent with the criteria for Meningococcal Infections (meningitis and bacteremia). The stakeholder also wanted to be sure that the case definition is clear for CRE. This is currently under review by the CDC and is not integral to the rule itself.

Stakeholders will have an additional opportunity to comment on the rules during the 30-day public comment period.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #4.a.

Approved by Assistant Commissioner/Director: Janna Zumbrun, Assistant Commissioner for DCPS Division

Presenter: Marilyn Felkner Program: Emerging and Acute Infectious Phone No.: 776-6393

Disease Branch

Approved by CCEA: Carolyn Bivens Date: 8/9/2013

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 97. Communicable Diseases
Subchapter A. Control of Communicable Diseases
Amendments §97.1, §97.3, §97.4, and §97.7

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §97.1, §97.3, §97.4, and §97.7, concerning the control of communicable diseases.

BACKGROUND AND PURPOSE

The amendments comply with Health and Safety Code, Chapter 81. The amendments will enable the reporting sources to more clearly identify the conditions and diseases that must be reported, define the minimal reportable information on these conditions and diseases, and describe the procedures for reporting. The amendments adjust the list of reportable diseases to include diseases and conditions of concern to public health. The conditions being added are newly emerging infectious conditions that have received international attention. Texas is complying with guidance from the Centers for Disease Control and Prevention regarding surveillance for these conditions. These amendments will allow the department to conduct more relevant and efficient disease surveillance.

SECTION-BY-SECTION SUMMARY

The amendments to §97.1, §97.3, and §97.4 add the reporting of Carbapenem resistant *Enterobacteriaceae* (CRE) and the reporting of Multi-drug Resistant (MDR) *Acinetobacter* as defined in the Centers for Disease Control and Prevention, National Healthcare Safety Network (NHSN) Manual, Patient Safety Component, Protocol for Multidrug-Resistant Organism and Clostridium difficile Infection (MDRO/CDI) Module, or its successor.

The amendments to §97.3 and §97.4 remove references to severe acute repository syndrome (SARS) and replace with the reporting of novel coronavirus causing severe acute respiratory disease because it is a broader category/definition that includes SARS. The disease novel influenza is placed in correct alphabetical order in §97.3.

In §97.1 and §97.7, the references to the legacy agency are updated.

The amendment to §97.7 updates exclusion criteria from a school for a student who has or is suspected of having a communicable condition, so that meningitis, bacterial and Meningococcal Infections (meningitis and bacteremia) are handled in a similar fashion.

FISCAL NOTE

Ms. Janna Zumbrun, Assistant Commissioner, Disease Control and Prevention Services, has determined that for each year of the first five years that the sections are in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Zumbrun has also determined that there will be no adverse economic costs to small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Zumbrun also has determined that for each year of the first five years the sections are in effect, the public will benefit from their adoption. These rules impact the people of Texas whose risk of illness is decreased by the early detection and control or prevention of infectious diseases in the community.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, \$2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed rules do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to David Rhinehart, Emerging and Acute Infectious Disease Branch, Infectious Disease Control Unit, Infectious Disease Prevention Section, Division for Disease Control and Prevention Services, Department of State Health Services, Mail Code 1960, P.O. Box 149347, Austin, Texas 78714-9347 or by email to

david.rhinehart@dshs.texas.gov. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized by Health and Safety Code, §81.004, which authorizes rules necessary for the effective administration of the Communicable Disease Prevention and Control Act; §81.042, which requires a rule on the exclusion of children from schools; §81.050 which requires a rule to prescribe criteria that constitute exposure to reportable diseases; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendments affect Government Code, Chapter 531, and Health and Safety Code, Chapters 81 and 1001.

Legend: (Proposed Amendment(s))

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

- §97.1. Definitions. The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.
 - (1) (2) (No change.)
- (3) Carbapenem resistant *Enterobacteriaceae* (CRE)--CRE-*Ecoli* or CRE-*Klebsiella* as defined in the Centers for Disease Control and Prevention, National Healthcare Safety Network (NHSN) Manual, Patient Safety Component, Protocol for Multidrug-Resistant Organism and Clostridium difficile Infection (MDRO/CDI) Module, or its successor.
- (4) [(3)] Carrier--An infected person or animal that harbors a specific infectious agent in the absence of discernible clinical disease and serves as a potential source or reservoir of infection.
- (5) [(4)] Case--As distinct from a carrier, the term "case" is used to mean a person or animal in whose tissues the etiological agent of a communicable disease is lodged and which usually produces signs or symptoms of disease. Evidence of the presence of a communicable disease may also be revealed by laboratory findings.
- (6) [(5)] Commissioner--Commissioner of the Department of State Health Services [Health].
- (7) [(6)] Common carrier--Any vehicle or device available to the public for transportation of persons, goods, or messages.
- (8) [(7)] Communicable disease--An illness due to an infectious agent or its toxic products which is transmitted directly to a well person from an infected person or animal, or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.
- (9) [(8)] Contact--A person or animal that has been in such association with an infected person or animal or a contaminated environment so as to have had opportunity to acquire the infection.
- $(\underline{10})$ [(9)] Diarrhea--A watery or loose stool that takes the shape of the container that holds it.
 - (11) **[(10)]** Department--Department of State Health Services.
- (12) [(11)] Disinfection--Application of chemical or physical agents to destroy infectious agents outside the body.

- (13) [(12)] Epidemic--The occurrence in a community or region of a group of illnesses of similar nature, clearly in excess of normal expectancy, and derived from a common or a propagated source.
- (14) [(13)] Exposure--A situation or circumstance in which there is significant risk of becoming infected with the etiologic agent for the disease involved.
- $(\underline{15})$ [(14)] Fever--A temperature of 100 degrees Fahrenheit (37.8 degrees Celsius) or higher.
- (16) [(15)] Health authority--A physician designated to administer state and local laws relating to public health under the Local Public Health Reorganization Act, Health and Safety Code, Chapter 121. The health authority, for purposes of this subchapter, may be:
 - (A) a local health authority appointed by the local government jurisdiction; or
- (B) a regional director of the Department of State Health Services if no physician has been appointed by the local government.
- (17) [(16)] Hospital laboratory--Any laboratory that performs laboratory test procedures for a patient of a hospital either as a part of the hospital or through contract with the hospital.
- (18) Multi-drug resistant (MDR) *Acinetobacter*--MDR-*Acinetobacter* as defined by the Centers for Disease Control and Prevention, National Healthcare Safety Network (NHSN) Manual, Patient Safety Component, Protocol for Multidrug-Resistant Organism and Clostridium difficile-Infection (MDRO/CDI) Module, or its successor.
- (19) [(17)] Notifiable condition--Any disease or condition that is required to be reported under the Act or by this chapter. See §97.3 of this title (relating to What Condition to Report and What Isolates to Report or Submit). Any outbreak, exotic disease, or unusual group expression of illness which may be of public health concern, whether or not the disease involved is listed in §97.3 of this title, shall be considered a "notifiable condition." The term "notifiable condition" is the same as the term "reportable disease" as used in the Health and Safety Code.
 - (20) [(18)] Outbreak--See definition of epidemic in this section.
- (21) [(19)] Pandemic--A global disease epidemic or an epidemic that crosses international borders and affects an extremely large number of people.
- (22) [(20)] Perinatal hepatitis B infection--HBsAg positivity in any infant aged >1-24 months.
- (23) [(21)] Physician--A person licensed by the Texas Medical Board to practice medicine in Texas.

- (24) [(22)] Physician assistant--A person licensed as a physician assistant by the Texas Physician Assistant Board.
- (25) [(23)] Regional director--The physician who is the chief administrative officer of a region as designated by the department under the Local Public Health Reorganization Act, Health and Safety Code, Chapter 121.
 - (26) [(24)] Report--Information that is required to be provided to the department.
- (27) [(25)] Report of a disease--The notification to the appropriate authority of the occurrence of a specific communicable disease in man or animals, including all information required by the procedures established by the department.
- (28) [(26)] Research facility--A facility that is licensed by the United States Department of Agriculture to use vertebrate animals for research purposes and is in compliance with the federal Animal Welfare Act (7 U.S.C., Chapter 54).
- (29) [(27)] School Administrator--The city or county superintendent of schools or the principal of any school not under the jurisdiction of a city or county board of education.
- (30) [(28)] Significant risk--A determination relating to a human exposure to an etiologic agent for a particular disease, based on reasonable medical judgments given the state of medical knowledge, relating to the following:
 - (A) nature of the risk (how the disease is transmitted);
 - (B) duration of the risk (how long an infected person may be infectious);
 - (C) severity of the risk (what is the potential harm to others); and
- (D) probability the disease will be transmitted and will cause varying degrees of harm.
- (31) [(29)] Specimen Submission Form--A current Department of State Health Services laboratory specimen submission form available from the Department of State Health Services, Laboratory Services Section, 1100 West 49th Street, Austin, Texas, 78756-3199.
- (32) [(30)] Vancomycin-intermediate resistant *Staphylococcus aureus* (VISA)-- *Staphylococcus aureus* with a vancomycin minimum inhibitory concentration (MIC) of 4 μ g/mL through 8 μ g/mL.
- (33) [(31)] Vancomycin-resistant *Staphylococcus aureus* (VRSA)--*Staphylococcus aureus* with a vancomycin MIC of 16 μ g/mL or greater.
- (34) [(32)] Veterinarian--A person licensed by the Texas State Board of Veterinary Medical Examiners to practice veterinary medicine in Texas.

- §97.3. What Condition to Report and What Isolates to Report or Submit.
 - (a) Humans.
 - (1) Identification of notifiable conditions.
- (A) A summary list of notifiable conditions and reporting time frames is published on the Department of State Health Services web site at http://www.dshs.state.tx.us/idcu/. Copies are filed in the Emerging and Acute Infectious Disease Branch, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.
- (B) Repetitive test results from the same patient do not need to be reported except those for mycobacterial infections.
 - (2) Notifiable conditions or isolates.
- (A) Confirmed and suspected human cases of the following diseases/infections are reportable: acquired immune deficiency syndrome (AIDS); amebiasis; amebic meningitis and encephalitis; anaplasmosis; anthrax; arboviral infections caused by California serogroup virus, Eastern equine encephalitis (EEE) virus, Powassan virus, St. Louis encephalitis (SLE) virus, Western equine encephalitis (WEE) virus, and West Nile (WN) virus; babesiosis; botulism-adult and infant; brucellosis; campylobacteriosis; carbapenem resistant Enterobacteriaceae (CRE); Chagas' disease; chancroid; chickenpox (varicella); Chlamydia trachomatis infection; Creutzfeldt-Jakob disease (CJD); cryptosporidiosis; cyclosporiasis; dengue; diphtheria; ehrlichiosis; shiga-toxin producing Escherichia coli infection; gonorrhea; Hansen's disease (leprosy); *Haemophilus influenzae* type b infection, invasive; hantavirus infection; hemolytic uremic syndrome (HUS); hepatitis A, B, C, and E, (acute); hepatitis B, (acute and chronic) identified prenatally or at delivery; perinatal hepatitis B infection; human immunodeficiency virus (HIV) infection; influenza-associated pediatric mortality; legionellosis; leishmaniasis; listeriosis; Lyme disease; malaria; measles (rubeola); meningococcal infection, invasive; [novel influenza;] multi-drug resistant (MDR) Acinetobacter-MDR; mumps; novel coronavirus causing severe acute respiratory disease; novel influenza; pertussis; plague; poliomyelitis, acute paralytic; poliovirus infection, non-paralytic; Q fever; rabies; relapsing fever; rubella (including congenital); salmonellosis, including typhoid fever; [severe acute respiratory syndrome (SARS) as defined by the United States Centers for Disease Control and Prevention;] shigellosis; smallpox; spotted fever group rickettsioses (such as Rocky Mountain spotted fever); streptococcal disease: invasive group A, invasive group B, or invasive Streptococcus pneumoniae; syphilis; Taenia solium and undifferentiated Taenia infections, including cysticercosis; tetanus; trichinosis; tuberculosis; tularemia; typhus; Vibrio infection, including cholera (specify species); viral hemorrhagic fevers; yellow fever; yersiniosis; and vancomycin-intermediate resistant Staphylococcus aureus (VISA), and vancomycin-resistant Staphylococcus aureus (VRSA).
 - (B) (No change.)
 - (3) (5) (No change.)

- (b) (No change.)
- §97.4. When to Report a Condition or Isolate.
 - (a) Humans.
- (1) The following notifiable conditions are public health emergencies and suspect cases shall be reported immediately by phone to the local health authority or the regional director of the Department of State Health Services (department): anthrax; botulism; carbapenem resistant Enterobacteriaceae (CRE); diphtheria; measles (rubeola); meningococcal infection, invasive; multi-drug resistant (MDR) Acinetobacter-MDR; novel coronavirus causing severe acute respiratory disease; poliomyelitis, acute paralytic; plague; novel influenza; rabies; [severe acute respiratory syndrome (SARS);] smallpox; tularemia; viral hemorrhagic fevers; yellow fever; and any outbreak, exotic disease, or unusual group expression of disease that may be of public health concern. Vancomycin-intermediate resistant Staphylococcus aureus (VISA) and vancomycin-resistant Staphylococcus aureus (VRSA) shall be reported immediately by phone to the Emerging and Acute Infectious Disease Branch, Department of State Health Services, Austin at (800) 252-8239.
 - (2) (6) (No change.)
 - (b) (No change.)
- §97.7. Diseases Requiring Exclusion from Schools.
- (a) The school administrator shall exclude from attendance any child having or suspected of having a communicable condition. Exclusion shall continue until the readmission criteria for the conditions are met. The conditions and readmission criteria are as follows:
 - (1) (14) (No change.)
- (15) meningitis, bacterial--<u>exclude until 24 hours after start of effective treatment and approval by health care provider</u> [exclude until written permission and/or permit is issued by a physician or local health authority];
 - (16) (No change.)
- (17) meningococcal infections (invasive disease)--exclude until 24 hours after start of effective treatment and approval by health care provider;
 - (18) [(17)] mumps--exclude until five days after the onset of swelling;
- (19) [(18)] pertussis (whooping cough)--exclude until completion of five days of antibiotic therapy;

- (20) [(19)] ringworm--none, if infected area can be completely covered by clothing or a bandage, otherwise exclude until treatment has begun;
- (21) [(20)] rubella (German measles)--exclude until seven days after rash onset or in the case of an outbreak, unimmunized children should be excluded until at least three weeks after the onset of the last rash;
- (22) [(21)] salmonellosis--exclude until diarrhea free for 24 hours without the use of diarrhea suppressing medications and fever free for 24 hours without the use of fever suppressing medications;
 - (23) [(22)] scabies--exclude until treatment has begun;
- (24) [(23)] shigellosis--exclude until diarrhea free for 24 hours without the use of diarrhea suppressing medications and fever free for 24 hours without the use of fever suppressing medications;
- (25) [(24)] streptococcal sore throat and scarlet fever--exclude until 24 hours from time antibiotic treatment was begun and fever free for 24 hours without the use of fever suppressing medications; and
- $(\underline{26})$ [(25)] tuberculosis, pulmonary--exclude until antibiotic treatment has begun and a physician's certificate or health permit obtained.
- (b) The school administrator shall exclude from attendance any child having or suspected of having a communicable disease designated by the Commissioner of <u>the Department of State Health Services</u> [Health] (commissioner) as cause for exclusion until one of the criteria listed in subsection (c) of this section is fulfilled.
 - (c) (No change.)